

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF IOWA**

**KATHY THOMAS AND JAMES  
THOMAS,**

**Plaintiffs,**

v.

**LIVANOVA DEUTSCHLAND  
GMBH (f/k/a SORIN GROUP  
DEUTSCHLAND GMBH) and SORIN  
GROUP USA, INC.**

**Defendants.**

**CIVIL ACTION**

**NO: 17-cv-360**

**JURY TRIAL DEMANDED**

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**CIVIL COMPLAINT**

Plaintiffs, Kathy Thomas and James Thomas, by way of Complaint against Defendants, LivaNova Deutschland GmbH and Sorin Group USA, Inc., allege as follows:

**JURISIDCTION AND VENUE**

1. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 USCS § 1332(a)(2). Plaintiffs are citizens and residents of the State of Iowa. Defendant, LivaNova Deutschland GmbH, is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA Inc. has a principal place of business in Arvada, Colorado.

2. Personal jurisdiction exists over Defendants, LivaNova Deutschland GmbH and Sorin Group USA, Inc., in the U.S. and in Iowa due to the general and specific contacts they maintain. Defendants maintain those contacts presently and did so at all times material to this action. The amount in controversy exceeds \$75,000.

3. Venue is proper in this District pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiffs' claims emanated from activities within this jurisdiction and Defendants conduct substantial business within this jurisdiction.

### **THE PARTIES**

4. Plaintiffs, Kathy Thomas and James Thomas, husband and wife, are adult individuals and citizens of the state of Iowa residing at 2830 Northview Drive, Marion, Iowa 52302.

5. Defendant, LivaNova Deutschland GmbH (formerly known as Sorin Group Deutschland GmbH) ("Sorin") is a foreign for profit corporation headquartered in Munich, Germany. Sorin designed, manufactured and marketed the Sorin 3T Heater-Cooler System.

6. Defendant, Sorin Group USA, Inc. ("Sorin USA") is a U.S. designer, manufacturer, marketer and distributor of the Sorin 3T Heater-Cooler System with a principal place of business in Arvada, Colorado.

### **GENERAL FACTUAL ALLEGATIONS**

#### **A. University of Iowa Hospitals and Clinics Announces Patient Exposure to Deadly Bacteria**

7. On or about February 2, 2016, the University of Iowa Hospitals and Clinics ("UIHC") announced that 1500 of its patients who had major heart, lung and liver surgeries between January 1, 2012 and January 22, 2016 had been exposed to a rare and potentially fatal bacteria via Sorin 3T Heater-Cooler Systems used to regulate blood temperature.

8. In addition to press releases, UIHC sent letters to individual patients which informed them of the exposure and advised follow up with their physicians.

9. The bacterium at issue, *M. Chimaera*, is a subspecies of nontuberculous mycobacterium (“NTM”) that occurs naturally in the environment and rarely causes illness. However, *M. Chimaera* poses a unique risk to patients whose organs and chest cavities are directly exposed to the bacteria during surgery.

10. Because *M. Chimaera* is a slow growing bacterium, it generally takes anywhere from several months to six years before manifestation of an *M. Chimaera* infection, which most commonly results in a heart infection known as endocarditis or disseminated infection spread throughout the body.

11. Symptoms of *M. Chimaera* infection are non-specific and may include any of the following: persistent fever, night sweats, joint and muscle pain, unexplained weight loss and fatigue.

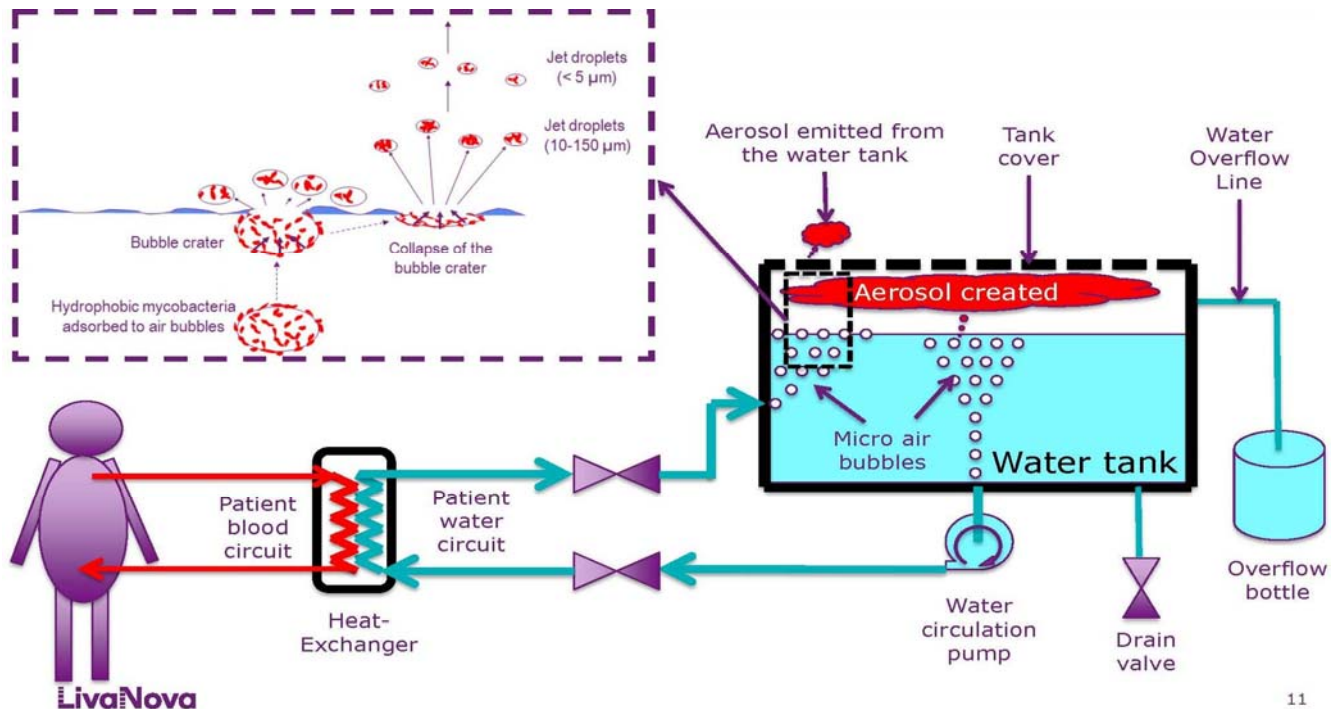
12. The diagnosis of an *M. Chimaera* infection requires targeted culturing and/or molecular diagnostic testing, the results of which take at least 6-8 weeks.

**B. Defendants’ 3T Heater-Cooler Systems as the Infection Source**

13. The Sorin 3T Heater Cooler Systems (“3T”) used at UIHC from January 1, 2012 to January 22, 2016 were designed, manufactured, marketed and/or sold by Defendants, Sorin and Sorin USA.

14. The 3T regulates blood temperature by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. The water tanks, and other areas where water passes through, aerosolize a vapor containing NTM which exits out of the device and is pushed into the ambient air of the operating room through the System’s exhaust fan.

If placed in the operating room, the contaminated vapor from the 3T directly enters the sterile surgical field and the patient's open body.



(taken from Defendants' publicly available presentation to the FDA Circulatory Devices Panel on June 2, 2016)

15. Published articles dating back to the 1980s confirm that NTM is commonly found in water and has a high propensity to become airborne (aerosolize) through natural processes.<sup>1</sup>

<sup>1</sup> See e.g., Wendt, *et al.*, Epidemiology of Infection by Nontuberculous Mycobacteria, III. Isolation of Potentially Pathogenic Mycobacteria from Aerosols, *American Review of Respiratory Disease*, 1980 ("Field experiments have confirmed the existence of a natural mechanism for the transfer of significant numbers of mycobacteria from water to air."); Falkinham, *Mycobacterial Aerosols and Respiratory Disease*, *Emerging Infectious Diseases*, July 2003 ("Environmental opportunistic Mycobacteria are present in drinking water, resistant to disinfection, able to provoke inflammatory reactions, and readily aerosolized.").

16. The potential for contaminated water from heater-cooler devices to infect patients intraoperatively was recognized by the medical and scientific community as early as November 2002.<sup>2</sup>

17. Invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.<sup>3</sup>

18. A public health investigation in Switzerland following six patient infections since 2011 included microbiological examinations of environmental samples that identified *M. Chimaera* contamination in heater-cooler units, including water samples from inside the units. Samples of the ambient air were positive for *M. chimaera* when the units were running, but negative when they were turned off.<sup>4</sup>

19. In April 2011, the FDA visited Defendant, Sorin, in Munchen, Germany for a plant inspection and to discuss safety concerns with several products, including the 3T approved in 2005 through the 510(k) process. The FDA advised the company that its 3Ts harbored dangerous bacteria and that it had failed to make a proper risk assessment for cleaning the devices to avoid bacterial infections in patients exposed in the operating room.

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<sup>2</sup> See The Heater-Cooler Unit—A Conceivable Source of Infection, Weitkemper, *et al.*, The Journal of the American Society of Extra-Corporeal Technology, 2002.

<sup>3</sup> ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at <http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf> (last accessed on June 20, 2017).

<sup>4</sup> Subsequent studies have further confirmed that the 3T aerosolizes *M. Chimaera* when powered on. See e.g., Lyman, *et al.* Invasive Nontuberculous Mycobacterial Infections among Cardiothoracic Surgical Patients Exposed to Heater-Cooler Devices, Emerging Infectious Diseases, May 2017; Gotting, *et al.*, Heater-Cooler Units: Contamination of Crucial Devices in Cardiothoracic Surgery, Journal of Hospital Infection, February 2016; Sommerstein, *et al.*, Transmission of *Mycobacterium Chimaera* from Heater-Cooler Units during Cardiac Surgery Despite an Ultraclean Air Ventilation System, Emerging Infectious Diseases, June 2016.

20. Defendants conceded to the FDA that this particular patient risk was “not considered” because it was “not of concern.”

21. During this inspection, the FDA advised the company that the bacterial growth charts it used to justify the original instruction for device disinfection every 14 days allowed bacterial overgrowth, well in excess of safe standards in just one and a half days. The company admitted to the FDA that its cleaning instructions did not meet these standards and that it had no information to support the cleaning methods it disseminated to U.S. purchasers.

22. More than four years later, on July 15, 2015, Defendants issued a Class 2 Recall of the 3T’s instructions for use (“IFU”) because of “[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use.”

23. The recall directed customers to follow the new cleaning and disinfection procedures outlined in a Field Safety Notice issued by Defendants on June 15, 2015.

24. According to this Field Safety Notice, the company’s hygiene concept was “enhanced”<sup>5</sup> by introducing the following modifications:

- a) Use filtered tap water when filling the device;
- b) To make disinfection easier, switch from three different cleaning procedures (every five days, every two weeks and every three months), to just two (every seven days and every fourteen days);
- c) The option to use peracetic acid instead of Clorox for disinfection;
- d) Use hydrogen peroxide in low dose for device preservation;

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<sup>5</sup> A month prior to the recall, in May 2015, Defendants informed customers that devices that had not been maintained according to the manufacturers’ IFUs required a mechanical deep disinfection process to remove bacterial colonization, referred to as “biofilm”.

- e) Include all external tubing, bottles and buckets in the disinfection process;
- f) Change to polyethylene tubing that meets national drinking water standards; and
- g) Unused heater-coolers should be disinfected bi-weekly.

25. Upon information and belief, Defendants knew or should have known that design and/or manufacturing defects in its 3T renders it prone to bacterial colonization and transmission, *regardless of the cleaning and disinfection procedures used.*<sup>6</sup>

26. Manufacturing and User Facility Device Experience (“MAUDE”) reports, such as one reported to the FDA on July 7, 2016, evidence that even mechanical deep disinfection followed by the use of filtered water, new water hoses, and three cycles of Defendants’ new cleaning procedure fail to eliminate high bacteria counts in the 3T.<sup>7</sup>

### **C. Additional NTM Outbreaks and Regulatory Agency Responses**

27. The risk of NTM transmission with the 3T is not unique to UIHC. In October and November 2015, two Pennsylvania hospitals notified approximately 3600 patients of their exposure to NTM through use of the 3T. On September 20, 2016, a third Pennsylvania hospital, Penn Presbyterian Medical Center in Philadelphia, announced patient infections linked to the 3T.

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<sup>6</sup> See e.g., Garvey, *et al.*, Decontamination of Heater-cooler Units Associated with Contamination by Atypical Mycobacteria, *Journal of Hosp. Infection*, March 2016 (finding that Defendants’ decontamination protocol was inadequate and that removal of internal tubing was required to achieve water quality in 3Ts); Marra, *et al.*, Mycobacterium Chimaera Infections Associated with Contaminated Heater-Cooler Devices for Cardiac Surgery: Outbreak Management, *Clinical Infectious Diseases*, April 19, 2017 (“Despite adherence to these [manufacturer] recommendations for use of sterile or filtered water, and regular water circuit disinfection and tubing changes, *M. Chimaera* contamination will persist...investigators using far more intensive attempts at disinfection have been unable to eradicate *M. Chimaera* from 3T HCDs.”)(internal citations omitted).

<sup>7</sup> See also, ECDC Rapid Risk Assessment, *supra* (“In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for *M. Chimaera* at the hospital tested positive three months after purchase and installation.”)

28. To date, there have been at least twenty-one (21) confirmed NTM infections in Pennsylvania which have resulted in five (5) deaths.

29. Hospitals in at least 14 other U.S. states have reported patient infections and/or device contamination with NTM. For example, in May 2016, Swedish Medical Center in Seattle, Washington issued letters notifying certain cardiac bypass patients that it had tested and found NTM in several of its 3Ts.

30. Many hospitals have either discontinued using the 3T or, like UIHC, have moved the device into a separate room to prevent contaminated aerosols from reaching the surgical field.

31. On October 21, 2015, following the first NTM outbreak in Pennsylvania, the U.S. Centers for Disease Control and Prevention (“CDC”) issued an Interim Practical Guidance communication to raise awareness among health departments, healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

32. On December 29, 2015, the FDA sent Defendants a warning letter advising that 3Ts were subject to refusal of admission into the U.S. until they resolved several FDA violations, including the FDA’s determination that the 3Ts were adulterated<sup>8</sup> and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions. The FDA’s findings were based on its inspections of the company’s Munchen, Germany and Arvada, Colorado production facilities.

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<sup>8</sup> Under the Federal Food, Drug and Cosmetic Act, a medical device is “adulterated” if the methods used in, or the facilities or controls used for their manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation.

33. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been documented, validated and/or submitted to the FDA for approval.

34. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, which had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

35. In April 2016, a Euro Surveillance study following environmental investigations conducted between July 2014 and June 2015 determined that certain 3Ts manufactured at Defendants' Munich, Germany production facility were contaminated with NTM on the production line or elsewhere at Defendants' manufacturing facility.

36. A June 1, 2016 FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the *M. Chimaera* to which European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model—the 3T." The FDA cautioned U.S. purchasers of the 3T that if they purchased their units before September 2014 they may have been shipped from Defendants' factory contaminated with *M. Chimaera*.<sup>9</sup>

37. In June 2016, a study published in the Journal of Emerging Infectious Diseases confirmed the airborne transmission of NTM via 3Ts due to the ability of the 3T's exhaust fan to disrupt the ultraclean air ventilation systems of operating rooms. According to the study,

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<sup>9</sup> June 1, 2016 FDA Safety Communication, available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm> (last accessed on June 20, 2017).

aerosolization from the 3T carried *M. Chimaera* particles a distance of up to 5 meters from the device.

38. On June 2-3, 2016, the FDA hosted a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the 3T.

39. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports (“MDR”) it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the 3T.



## MDRs by Manufacturer, Brand Name and User Facility (US vs. OUS)

MDRs by Manufacturer and UF				
Manufacturer and Brand Name	Total Number of MDRs	Number of User Facilities Represented in the MDRs		
		US	OUS	Total
LivaNova/Sorin** Stockert 3T	160	15	35	50
Maquet HCU20, HCU30 & HCU40	9	0	5*	5*
Cincinnati Sub-Zero 333W and Hemotherm	3	2*	0	2*
Terumo HX2	8	1*	0	1*
<b>Total</b>	<b>180</b>	<b>16 (2*)</b>	<b>39 (1*)</b>	<b>55 (3*)</b>

\*Note that 3 UF reported devices from 2 different manufacturers

\*\*LivaNova/Sorin has approximately 60% of the market share for this type of device

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40. During this Panel, Defendants’ representatives admitted that the company was in the process of retrofitting existing 3Ts with new design features, including, but not limited to,

changing tubing materials from PVC to polyethylene to limit biofilm formation and the introduction of plugs in the water circuit to prevent sitting water.

41. On October 13, 2016, the CDC released the results of genome sequencing studies confirming that patient infections in Pennsylvania and Iowa were directly linked to Defendants' Munich, Germany manufacturing site.<sup>10</sup>

42. That same day, the FDA issued an updated Safety Communication instructing hospitals throughout the country to discontinue using 3Ts manufactured before September 2014 due to evidence of "point source contamination at the production site".<sup>11</sup>

43. Subsequent studies published in 2017 further confirm "an ongoing international outbreak of *M. Chimaera* infection following cardiac surgery" and that "all *M. Chimaera* infections have been attributed to a specific make/model of HCU (Sorin 3T, LivaNova PLC, formerly Sorin Group Deutschland GmbH).<sup>12</sup>

### **FACTUAL ALLEGATIONS SPECIFIC TO PLAINTIFF, KATHY THOMAS**

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<sup>10</sup> See CDC Morbidity and Mortality Weekly Report for October 14, 2016, available online at [https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s\\_cid=mm6540a6\\_w](https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w) (last accessed on June 20, 2017). Multiple studies have since linked the same strain of *M. Chimaera* to patient infections following use of the 3T in geographically sequestered locations such as Australia, Canada, France, Germany, Hong Kong, Ireland, the Netherlands, Spain and Switzerland. See e.g., Svensson, *et al.*, *Mycobacterium chimaera* in heater-cooler units in Denmark related to isolates from the United States and United Kingdom, *Emerg Infect Dis.*, March 2017, available online at [https://wwwnc.cdc.gov/eid/article/23/3/16-1941\\_article](https://wwwnc.cdc.gov/eid/article/23/3/16-1941_article) (last accessed on June 20, 2017); see also Walker, *et al.*, Microbiological Problems and Biofilms Associated with Mycobacterium Chimaera in Heater-cooler Units Used for Cardiopulmonary Bypass, *Journal of Hospital Infection*, April 26, 2017 (collecting data of global *M. Chimaera* infections).

<sup>11</sup> See October 13, 2016 "UPDATE: Mycobacterium Chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T Heater-Cooler System: FDA Safety Communication", available online at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm> (last accessed on June 20, 2017)

<sup>12</sup> See e.g., Walker, *et al. supra*; Lyman, *et al. supra* (detailing a Pennsylvania field investigation which "confirmed a prolonged outbreak of invasive MAC infections associated with cardiac surgery requiring cardiopulmonary bypass with exposure to 3T HCDs, similar to reports from Europe.")

44. On November 28, 2015, Kathy Thomas experienced severe chest pain and shortness of breath. Kathy Thomas was admitted to Mercy Medical Center in Des Moines, Iowa then transferred to UIHC for emergency surgery after a CT scan showed intramural hematoma of the ascending and descending aorta.

45. On November 29, 2015, Kathy Thomas underwent open heart surgery at UIHC for repair of aortic dissection with proximal and distal neo-intimal reconstruction with an aortic graft.

46. Early in 2016, Kathy Thomas received a letter dated February 1, 2016 from UIHC notifying her of the possible risk of Nontuberculous Mycobacteria (NTM) infection from the use of heater cooler devices at UHIC.

47. Beginning in the summer of 2016, Kathy Thomas experienced vision changes and temporary loss of eye sight from choroidal lesions in both eyes, pain in both eyes, and large floaters shooting in her eyes.

48. Kathy Thomas began to experience additional symptoms in or about November of 2016, including drenching night sweats, nausea, fatigue, joint and muscle pain, chest pain, decreased appetite, unexplained weight loss, and shortness of breath. As a result, she consulted with her physician.

49. On January 20, 2017, Kathy Thomas was seen by infectious disease physicians of UIHC for further evaluation of a possible *M. Chimaera* infection and UIHC physicians took a series of samples to test for NTM.

50. During a January 20, 2017 consult with UIHC physicians, physicians noted that “a LivaNova (Sorin) [3T] heater cooler device was used during her procedure, and these devices have now been associated with a world-wide outbreak of Mycobacterium chimaera infections.”

51. On January 20, 2017, Kathy Thomas was also referred to an ophthalmologist for her visual symptoms and diagnosed with choroiditis from *Mycobacterium Chimaera* chorioretinitis.

52. In or about early February 2017, Kathy Thomas' blood cultures grew M. Avium Complex (NTM) and she underwent further testing.

53. In February 2017, Kathy Thomas was prescribed and began taking a three medication antimycobacterial therapy to treat M. Avium Complex infection. While on the medication, Kathy Thomas did not show improvement in her symptoms.

54. In April 2017, infectious disease physicians informed Kathy Thomas that her tissue cultures were positive for NTM, specifically *M. Chimaera*. Physicians intensified her antimycobacterial therapy to a quintuple antibiotic therapy plan.

55. On April 27, 2017, Kathy Thomas was admitted to UIHC. As a result of her ongoing symptoms and diagnosis of disseminated *M. Chimaera* infection with aortic graft and prosthetic aortic valve infection, Kathy Thomas underwent extensive surgical procedures for aortic root replacement, resection and replacement of the ascending aorta and reconstruction of the right and left main coronary artery.

56. During the April 27, 2017 surgery, Kathy Thomas suffered from hemorrhagic shock and acute cardiogenic shock with pulmonary edema. She also suffered an acute kidney injury.

57. Kathy Thomas was discharged from UIHC on May 8, 2017 and continued her antibiotic regimen.

58. To date, Kathy Thomas continues to undergo treatment including, but not limited to, intravitreal injections and an antimycobacterial antibiotic regimen. Additionally, Kathy Thomas undergoes periodic testing to evaluate for *M. Chimaera*.

59. Kathy Thomas' physicians anticipate she will continue to require her antimycobacterial antibiotic regimen for approximately twelve to eighteen additional months.

60. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Kathy Thomas acquired an *M. Chimaera* infection, forcing her to undergo painful medical procedures and treatment, including, but not limited to, multiple bone marrow biopsies, quintuple antibiotic therapy and extensive surgical procedures to repair the damage from her infection.

61. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff, Kathy Thomas expended, and continues to expend, various sums of money for medical care and treatment.

62. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff, Kathy Thomas, suffered, and continues to suffer, from excruciating and agonizing physical and emotional pain.

63. Plaintiff, Kathy Thomas, was in no way responsible for her injuries.

**COUNT I**  
**Negligence- Design Defect**

64. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

65. The 3T is a product within the meaning of Iowa products liability law.

66. The 3T was expected to reach, and did reach, users and/or consumers, including Plaintiff, Kathy Thomas, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

67. Under Iowa products liability law, Defendants, Sorin and Sorin USA owed Plaintiff a duty to exercise reasonable care in designing and testing the 3T.

68. Defendants, Sorin and Sorin USA, designed the 3T for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

69. At all times material, the 3T was used in a manner intended and/or foreseeable to the Defendants.

70. A patient or consumer using the 3T would reasonably expect the device to be free of significant defects.

71. The 3T, as designed by the Defendants, colonizes bacteria, including *M. Chimaera*.

72. The 3T, as designed by the Defendants, directly transmits bacteria, including *M. Chimaera*, to patients during invasive surgery.

73. The foreseeable risks of using the 3T, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T.

74. Reasonable alternative designs existed for the 3T which would have eliminated or reduced the risk of bacterial colonization and/or transmission of such bacteria to patients undergoing invasive surgical procedures.

75. Reasonable and feasible alternative designs include, but are not limited to, measures to direct airflow away from the surgical field (i.e. a housing unit for the exhaust vent), reducing the force at which air is vented from the System to a rate of less than 1000 cubic feet per minute,

water reservoir isolation by using closed loop fluid management, an open water design to prevent inaccessible airspace, removable lids and parts for easy disinfection, disposable tank liners to prevent biofilm formation, and internal pasteurization or UV features to kill bacteria.

76. The failure to use feasible, reasonable alternative designs that eliminate bacterial colonization and the aerosolization of bacteria into the ambient air of operating rooms renders the 3T unreasonably unsafe.

77. Defendants knew or should have known that NTM, or other harmful bacteria, could colonize within the 3T and be spread to patients during surgery through the exhaust vent.

78. Plaintiff, Kathy Thomas' *M. Chimaera* infection was caused by Defendants' conduct as follows:

- a) Failing to conduct adequate safety and efficacy testing before placing the 3T into the stream of commerce;
- b) Failing to timely establish procedures for reviewing the design of the 3T after receiving information that patients were developing bacterial infections as a result of surgeries using the 3T;
- c) Failing to timely establish procedures for validation or, where appropriate, review and approval of design change orders for the 3T before their implementation as required under 21 CFR 820.30(i); and
- d) Failing to design or redesign the 3T to eliminate or mitigate bacterial colonization and/or transmission of such bacteria.

79. Plaintiff, Kathy Thomas, was proximately harmed by the design defects in the 3T as described above.

WHEREFORE, Plaintiffs, Kathy and James Thomas, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

**COUNT II**  
**Strict Liability-Manufacturing Defect**

80. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

81. The 3T is a product within the meaning of Iowa products liability law.

82. The 3T was expected to reach, and did reach, users and/or consumers, including Plaintiff, Kathy Thomas, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

83. Defendants, Sorin and Sorin USA manufactured the 3T for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

84. At all times material, the 3T was used in a manner intended and/or foreseeable to the Defendants.

85. A reasonable patient or consumer of the 3T would expect that the device be free of significant defects.

86. The 3T, as manufactured by the Defendants, colonizes bacteria, including *M. Chimaera*.

87. The 3T, as manufactured by the Defendants, directly transmits bacteria, including *M. Chimaera*, to patients during invasive surgery.

88. The foreseeable risks of using the 3T, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T.

89. Plaintiff, Kathy Thomas' *M. Chimaera* infection was caused by Defendants' conduct as follows:

- a) Failing to timely establish procedures or practices to prevent the 3T from being contaminated with NTM on the production line or elsewhere at Defendants' production facilities;
- b) Manufacturing and selling the 3T with NTM contamination that occurred on the production line or elsewhere at Defendants' production facilities; and
- c) Failing to ensure proper workmanship, materials and labeling for the 3T.

90. Plaintiff, Kathy Thomas, was proximately harmed by the manufacturing defects in the 3T as described above.

WHEREFORE, Plaintiffs, Kathy and James Thomas, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

**COUNT III**  
**Negligence- Warnings Defects**

91. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

92. The 3T is a product within the meaning of Iowa products liability law.

93. The 3T was expected to reach, and did reach, users and/or consumers, including Plaintiff, Kathy Thomas, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

94. Defendants, Sorin and Sorin USA, owed Plaintiff, Kathy Thomas, a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling the 3T.

95. Defendants, Sorin and Sorin USA marketed, advertised and promoted the 3T for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

96. At all times material, the 3T was used in a manner intended and/or foreseeable to the Defendants.

97. A reasonable patient or consumer of the 3T would expect that the device be free of significant defects.

98. The 3T colonizes bacteria, including *M. Chimaera*, and directly transmits such bacteria to patients during invasive surgery.

99. Defendants knew or should have known that NTM, or other harmful bacteria, could colonize within the 3T and be spread to patients during surgery through the exhaust vent.

100. The foreseeable risks of using the 3T, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T.

101. Plaintiff, Kathy Thomas' *M. Chimaera* infection was caused by Defendants' conduct as follows:

- a) Failing to provide proper cleaning and disinfection procedures for the 3T;
- b) Failing to conduct proper validation studies to demonstrate the safety and efficacy of cleaning and disinfection procedures for the 3T;

- c) Failing to warn patients like Kathy Thomas and/or purchasers of the 3T that the device colonized bacteria and unnecessarily transmitted it into the ambient air of operating rooms;
- d) Failing to timely notify known purchasers of the 3T that patients could be exposed to NTM;
- e) Failing to alert hospitals and patients to promptly test for NTM infection when patients present with fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss and fatigue after surgery using the 3T; and
- f) Failing to timely notify known purchasers of the 3T to relocate the device from the operating room during surgery to prevent patient transmission of NTM.

102. Plaintiff, Kathy Thomas, was proximately harmed by the warnings defects in the 3T as described above.

WHEREFORE, Plaintiffs, Kathy and James Thomas, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

**COUNT IV**  
**Loss of Spousal Consortium**

103. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

104. Plaintiff, James Thomas, is entitled to the care, comfort, companionship, services, and consortium of his wife, Kathy Thomas. As a result of the aforesaid injuries sustained by Kathy

Thomas, Plaintiff, James Thomas has been and will continue to be deprived of the care, companionship, services and consortium of his wife.

WHEREFORE, Plaintiff, James Thomas, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

**PRAYER FOR RELIEF**

Plaintiff, Kathy and James Thomas, requests the Court to enter judgment against the Defendants as follows:

- A. An award to Plaintiff of compensatory and punitive damages, costs and reasonable attorneys' fees, as permitted by law;
  - B. An award of pre-judgment and post-judgment interest, as provided by law;
  - C. Leave to amend this Complaint to conform to the evidence produced at trial;
- and
- D. Such other relief as may be appropriate under the circumstances.

**JURY TRIAL DEMANDED**

Plaintiff demands a trial by jury on all issues so triable.

Dated: October 6, 2017

Respectfully submitted,

**WRIGHT & SCHULTE, LLC**

/s/ Richard W. Schulte  
Richard W. Schulte  
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